

REMARKS/ARGUMENTS

Reconsideration of the present application, as amended, is respectfully requested.

Since the present amendment raises no new issues for consideration and, in any event, places the present application in better condition for consideration on appeal, it is respectfully requested that this amendment be entered under 37 CFR 1.116 in response to the last Office Action dated March 6, 2006, which made final rejections as to the pending claims.

Please change the attorney docket number to 224.0503 and acknowledge the appointment of the undersigned as attorney of record and for further correspondence.

Claims 2, 3 and 13 have been amended to address typographical errors. No new matter has been added. Applicants reserve the right to present the cancelled claims in one or more divisional applications.

The undersign wishes to thank the Examiner for the courtesies extended during the telephone interview conducted May 2, 2006.

The claimed invention is directed to a composition containing and active agent having at least one nitrogen containing moiety and an amount of glycyrrhizin which complexes with the active agent so that the dosage form is substantially free of uncomplexed active agent. As a result of the complex being formed, there is an increased solubility of the active agent.

As was pointed out during the telephone interview, it is well known that glycyrrhizin is typically used as a flavoring agent or sweetener. As such, it is typically present in amounts which are substantially lower than the amount of the active agent. Moreover, there is mere admixture or dry blending of the sweetener with all of the other ingredients. The prior art fails to show complexation of the glycyrrhizin with the active agent, let alone that it is desirable or that there would be advantages by forming such complexes. In view of these facts, the prior art also

does not disclose compositions containing not only the glycyrrhizin and active agent complexes but compositions which are substantially free of the uncomplexed active agent.

As was also pointed out in the telephone interview, both of the references relied upon by the Examiner disclose the use of glycyrrhizin as a sweetener either in a gum or an intrabuccal device.

In the final office action, the Examiner stated that the burden has shifted to applicant to show some unexpected result. In response thereto, applicants again point to the fact that complexation of the active agent with the glycyrrhizin achieves increased solubility of the active and this is unexpected. It is not related to any degree of taste masking or sweetening. Indeed, the Examiner indicated in the office action that the complexation was missing from the references. As such, there is no disclosure or suggestion in either of the references to form such complexes and there would be no motivation to do so without the use of impermissible hindsight on the part of the Examiner. It is respectfully submitted, therefore, that the claims as presented herein are patentability distinguishable over each of the above mentioned references.

For the sake of completeness, Applicants wish to address the Examiner's statement found on page 4, fourth paragraph of the office action concerning the Applicants establishing criticality of the formulation being free of uncomplexed active agent. One of the keys to the claimed invention is the fact that the pharmaceutical composition contains complexed active agents. It is the complexed active agents which have improved solubility as opposed to the uncomplexed forms. It will be apparent to those of ordinary skill that pharmaceutically elegant compositions are those which will have uniform solubility and thus predictable absorption after dosing. This desirable property will happen in those aspects where there is sufficient glycyrrhizin to allow full complexation with the active present in the composition.

REJOINER REQUESTED

Applicants request that the Examiner rejoin those claims withdrawn previously from consideration in this application. It is believed that the claims for which this rejoinder is requested meet all of the criteria for patentability and that they are of a scope commensurate with the claim from which they depend.

PROVISIONAL REQUEST FOR EXTENSION OF TIME

This response is being filed with a two month extension of time. No further fee is believed to be due. If, on the other hand, it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275. Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

CONCLUSION

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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